



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 18, 2020

Kevin Kutcel
Agent for Innovaycin, Inc.
KRR Consulting LLC
5807 Churchill Way
Medina, OH 44256

Subject: PRIA Label Amendment – New Public Health Organisms and Addition of
Emerging Viral Pathogen Claims
Product Name: 275 TBD
EPA Registration Number: 88373-1
Application Date: June 4, 2020
Decision Number: 563500

Dear Mr. Kutcel:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the [August 19, 2016, Guidance To Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels \(“Guidance”\)](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:

- a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - b. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is [small non-enveloped, large non-enveloped, enveloped].
 - c. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term B.3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term B.3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term B.3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.
 5. Terms B.1 through B.4 above shall become immediately void and ineffective if registration for use against *Norovirus (as Feline calicivirus)* ATCC VR-782, strain F9 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Daniel Schoeff by phone at 703-347-0143, or via email at schoeff.daniel@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Jacqueline Hardy".

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II,
Antimicrobials Division (7510P)

Enclosure: Stamped Label

275 TBD

{Alternate Brand Names: Sanacyn DX; Vetericyn Surface DX;
SKV Disinfectant; SKV DX}

Hypochlorous Acid Solution Generated Electrochemically from Sodium Chloride

275 TBD is:

- a cost-effective disinfecting solution;
- produced with low energy and low costs from water and salt;
- produced in a single-stage process by a simple electrolytic cell;
- produced for use in medical, institutional, industrial and commercial applications and
- produced with a controlled pH and controlled concentration of Free Available Chlorine (FAC).

ACTIVE INGREDIENT:	
Hypochlorous Acid	0.0275%
OTHER INGREDIENTS:	<u>99.9725%</u>
TOTAL:	100.0000%

Contains 275ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

See Back Panel for Precautionary Statements

EPA Reg. No. 88373-1

Est. No. xxxxx-xx-x

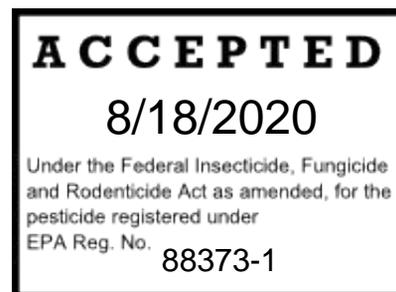
Manufactured by:

Innovacyn, Inc.
3546 North Riverside Avenue, Rialto, CA 92377
Phone No: +1.888.592.7844

275 TBD must be used within 30 days after production.

DATE PRODUCED: _____

Net Contents: _____



275 TBD is a Hypochlorous Acid solution produced by passing an aqueous saline solution (brine) through 1 or more electrolytic cells. The current within the electrolytic cell(s) splits the sodium chloride compound into two separate fluids. One fluid is Hypochlorous Acid, a powerful oxidizing agent exhibiting antimicrobial properties.

275 TBD is produced at a near neutral pH, (approximately pH 6.5) where the predominant antimicrobial agent is Hypochlorous Acid, an efficient and efficacious species of chlorine.

275 TBD properties are closely controlled by controlling the voltage and the current to the electrolytic cell(s), brine conductivity, temperature and flow rate through the cells as well as the pH of the Hypochlorous Acid generated in the cell(s).

275 TBD freezes at 32°F and boils at 212°F. It is a colorless and aqueous solution with a slight chlorine or ozone odor.

After production, **275 TBD** must be stored in a closed plastic container in a cool and dark area away from direct sunlight.

275 TBD is intended to be used soon after being produced.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Hard, Non-Porous Surface Disinfection

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For visibly soiled areas, a preliminary cleaning is required. Apply 275 TBD to hard, non-porous surfaces using a cloth, sponge, wipe, mop, sprayer or by dipping. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Do not use on utensils, glasses or dishes.

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

Pathogen	Strain	Contact Time
<i>Pseudomonas aeruginosa</i>	ATCC 15442	10 minutes
<i>Staphylococcus aureus</i>	ATCC 6538	10 minutes
<i>Salmonella enterica</i>	ATCC 10708	10 minutes
<i>Human Coronavirus</i>	ATCC VR-740, Strain 229E	10 minutes
<i>Norovirus (as Feline Calicivirus)</i>	ATCC VR-782, Strain F-9	10 Minutes

EMERGING VIRAL PATHOGENS CLAIMS

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This Product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped Virus	Norovirus (as Feline Calicivirus)
Large, non-enveloped virus	Norovirus (as Feline Calicivirus)

275 TBD has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, 275 TBD can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. 275 TBD kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

CLAIMS

- + Broad Spectrum Disinfectant
- + One-Step Cleaner / Disinfectant when Disinfection Directions are followed
- + Aids in the Reduction of Cross-Contamination between Treated Surfaces
- + This Disinfection Process assures Proper Strength, Product Effectiveness and Standardizes Technique
- + Formulated for Bacteria Fighting
- + Bactericide - or - Bactericidal
- + Bathroom Disinfectant
- + Nursery Disinfectant
- + Athletic Facility Disinfectant
- + Cleans and Disinfects Site(s) on Tables 1–4 below
- + Cleans and Disinfects Hard, Non-Porous Surfaces
- + Cleans, Deodorizes and Disinfects
- + Deodorizes by Killing Odor-Causing Bacteria
- + Disinfecting Formula

- + Disinfects and Deodorizes by Killing Bacteria and their Odors
- + Eliminates - or - Reduces Odors caused by Bacteria
- + Eliminates odors at their source; bacteria
- + Disinfects Hard, Non-Porous Surfaces on Site(s) on Tables 1–4 below
- + Easy and Convenient Disinfecting on Site(s) on Tables 1–4 below
- + Easy One-Step Cleaning and Disinfecting when Disinfection Directions are followed
- + Effective against - or - Kills Organism(s) mentioned in Table on Page 2 above
- + Effectively Disinfects Hard, Non-Porous, Environmental Surfaces
- + Fight(s) - and/or - Kill(s) - and/or - Effective against *Salmonella enterica*
- + Fight(s) - and/or - Kill(s) - and/or - Effective against *Staphylococcus aureus*
- + Fight(s) - and/or - Kill(s) - and/or - Effective against *Pseudomonas aeruginosa*
- + Fight(s) - and/or - Prevent(s) Cross-Contamination between treated Hard, Non-Porous Surfaces on Tables 1–4 below
- + Kills Odor-Causing Bacteria mentioned in Table on Page 2 above
- + Kills - or - Effective against Bacteria mentioned in Table on Page 2 above
- + Multi-Purpose Disinfectant
- + One-Step Cleaner and Disinfectant when Disinfection Directions are followed
- + One-Step Cleaner and Disinfectant (when Disinfection Directions are followed) designed for General Cleaning and Disinfecting Hard, Non-Porous Environmental Surfaces in Health Care Facilities and on Sites listed on Tables 1–4 below
- + Pseudomonocidal*
- + Staphylocidal**
- + Ready-to-Use Hospital Disinfectant
- + The Answer to your Disinfecting Needs
- + The Easy - and/or - Convenient way to Disinfect
- + This Product controls Cross-Contamination between treated Hard, Non-Porous Surfaces
- + This Product was tested according to AOAC Test Methods
- + Use in Public - or - Common Places where Bacteria may be of concern on Hard, Non-Porous Surfaces
- + Use where Control of the Hazards of Cross-Contamination between Treated Hard Non-Porous Surfaces is of Importance
- + Use in Public - or - Common Places where Bacteria may be of concern on Hard, Non-Porous Surfaces
- + Use where Control of the Cross-Contamination between Treated Hard Non-Porous Surfaces is of Importance

* *Pseudomonas aeruginosa* (ATCC 15442)

** *Staphylococcus aureus* (ATCC 6538)

GENERAL CLAIMS

- + Convenient
- + For General Use
- + For Use on Nursery Surfaces
- + Suitable for Hospital Use
- + For Use on Bathroom Surfaces
- + For Use in Athletic Facilities
- + Easy to Handle
- + For Use on Athletic Equipment
- + Will not Harm Surfaces listed on Tables 1 – 4
- + Will not Harm Hard, Non-Porous Inanimate Environmental Surfaces
- + Will not Harm Titanium-Coated, Medical Grade Stainless Steel

SURFACE MATERIALS

- + Baked enamel
- + Chrome
- + Common Hard, Non-Porous Household - or - Environmental Surfaces
- + Formica
- + Glass
- + Glazed Ceramic Tile
- + Glazed Porcelain
- + Glazed Porcelain Enamel
- + Laminated Surfaces
- + Plastic Laminate
- + Stainless Steel
- + Synthetic Marble
- + Vinyl Tile
- + Similar Hard, Non-Porous Surfaces except those excluded by the label

Not Recommended For Use On - or - Avoid Contact With

- + Aluminum Brass
- + Chipped enamel
- + Clear plastic
- + Clothes
- + Copper
- + Fabrics
- + Gold
- + Natural marble
- + Natural rubber
- + Painted surfaces
- + Paper surfaces
- + Sealed granite
- + Silver
- + Unfinished wood
- + Wood

TABLE ONE: Medical Environments

USE SITES

- + Ambulances - or - Emergency Medical Transport Vehicles
- + Anesthesia Rooms - or - Areas
- + Assisted Living - or - Full Care Nursing Homes
- + CAT Laboratories
- + Central Service Areas
- + Central Supply Rooms - or - Areas Critical Care Units - or - CCUs
- + Dialysis Clinics
- + Emergency Rooms - or - RS (Registered Sanitarian) Health Care Settings –
or Facilities
- + Home Health Care Settings
- + Hospitals
- + Intensive Care Units - or - ICU Laboratories
- + Medical - or - Physician's - or - Doctor's Offices Newborn - or - Neonatal
Nurseries
- + Medical Clinics
- + Medical Facilities
- + Nursing - or - Nurses' Stations
- + Orthopedics
- + Outpatient Clinics
- + Patient Restrooms
- + Patient Rooms
- + Pediatric Examination Rooms - or - Areas
- + Pharmacies
- + Physical Therapy Rooms - or - Areas
- + Radiology - or - X-Ray Rooms - or - Areas
- + Surgery Rooms - or - Operating Rooms - or ORs

SURFACES (Applicable to materials listed under **Surface Materials**)

- + Bed pans
- + Exam - or - Examination Table:
- + External Surfaces of Medical Equipment - or - Medical Equipment Surfaces
- + External Surfaces of Ultrasound Transducers
- + Gurneys
- + Hard, Non-Porous Environmental Hospital - or - Medical Surfaces
- + Hospital - or - Patient Bed Railings - or - Linings - or - Frames
- + IV Poles
- + Patient Chairs
- + Plastic Mattress Covers
- + Reception Counters - or - Desks - or - Areas
- + Stretchers
- + Wash Basins

- + Wheelchairs

TABLE TWO: Dental Environment:

USE SITES

- + Dental - or - Dentist's Offices
- + Dental Operatory rooms

SURFACES (Applicable to materials listed under **Surface Materials**)

- + Dental Countertops
- + Dental Operatory Surfaces
- + Dentist - or - Dental Chairs
- + Hard, Non-Porous Environmental Dental Surfaces
- + Light Lens Covers
- + Reception Counters - or - Desks - or – Areas

TABLE THREE: Veterinary Environments:

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water.

Apply **275 TBD** and saturate surfaces with solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.

After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

USE SITES

- + Animal - or - Pet Grooming Facilities Kennels
- + Animal Housing Facilities
- + Animal Life Science Laboratories
- + Livestock - and/or - Swine - and/or - Poultry Facilities
- + Pet Areas
- + Pet Shops - or - Stores
- + Small Animal Facilities
- + Veterinary - or - Animal Hospitals
- + Veterinary Clinics - or - Facilities

+ Veterinary Offices

SURFACES (Applicable to materials listed under **Surface Materials**)

- + Animal Equipment Automatic Feeders
- + Cages
- + External Surfaces of Veterinary Equipment
- + Feed Racks
- + Fountains
- + Hard, Non-Porous Environmental Veterinary Surfaces
- + Pens
- + Reception Counters - or - Desks - or - Areas Stalls
- + Troughs
- + Veterinary Care Surfaces
- + Watering Appliances

TABLE FOUR: Miscellaneous / General Environments

USE SITES

- + Airplanes
- + Blood Banks
- + Boats
- + Bowling Alleys
- + Chillers
- + Churches
- + Colleges
- + Correctional Facilities
- + Cruise Lines
- + Day Care Centers
- + Dormitories
- + Factories
- + Funeral Homes
- + Grocery Stores
- + Gymnasiums - or - Gyms
- + Health Club Facilities
- + Hotels
- + Industrial Facilities
- + Laundromats
- + Laundry Rooms Locker Rooms
- + Manufacturing Facilities
- + Manufacturing Plants - or - Facilities
- + Military Installations
- + Motels

- + Preschool Facilities
 - + Public Areas
 - + Recreational Centers - or - Facilities
 - + Restrooms - or - Restroom Areas
 - + School Buses
 - + Schools
 - + Shelters
 - + Shower Rooms
 - + Storage Rooms - or - Areas
 - + Supermarkets
 - + Trains
 - + Universities
 - + Wineries
 - + Yachts
- SURFACES* (Applicable to materials listed under **Surface Materials**)

- + Bathroom Fixtures
- + Bath Tubs
- + Behind and under Counters
- + Behind and under Sinks
- + Booster Chairs
- + Cabinets Ceilings
- + Cellular - or - Wireless - or - Mobile - or - Digital Phones
- + Chairs
- + Computer Keyboards
- + Computer Monitors
- + Counters - or - Countertops
- + Cribs
- + Desks
- + Diaper - or - Infant Changing Tables
- + Diaper Pails
- + Dictating Equipment Surfaces
- + Doorknobs
- + Exterior - or - External Toilet Surfaces
- + Exterior - or - External Urinal Surfaces
- + Faucets
- + Floors
- + Garbage - or - Trash Cans
- + Grocery Store - or - Supermarket Carts
- + Hampers

- + Hand Railings
- + Headsets
- + Highchairs
- + Lamps
- + Linoleum
- + Playpens
- + Shelves
- + Showers - or - Shower Stalls
- + Sinks
- + Stall Doors
- + Tables
- + Telephones
- + Tiled Walls
- + Toilet Rims
- + Toilet Seats
- + Towel Dispensers
- + Toys
- + Vanity Tops - or - Vanities
- + Other Telecommunications Equipment Surfaces

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

For Industrial and Commercial Use Packages:

Pesticide Storage: Store in a closed dark plastic container in a cool, dry area away from heat and sunlight. Do not store near easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with water to dissolve all material before discarding this container in trash.

Emergency Handling: In case of contamination or decomposition. Do not reseal container. Isolate in open, well-ventilated area. Flood with large amounts of water. Cool unopened containers in vicinity by water spray.

Pesticide Disposal: Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environment Control Agency, or the Hazardous Waste Representative at the EPA Regional Office for guidance.

(For non-refillable containers 5 gallons or less):

Container Handling: Non-refillable container. Do not reuse or refill this

container. Triple-rinse container (or equivalent) promptly after emptying. Triple-rinse as follows: Empty the remaining contents into the application equipment or a mix tank. Fill the container $\frac{1}{4}$ with water and recap. Shake for 10 seconds. Pour rinsate into the application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure 2 more times. Then offer for recycling or reconditioning if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(For non-refillable containers larger than 5 gallons):

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple-rinse container (or equivalent) promptly after emptying. Triple-rinse as follows: Empty the remaining contents into the application equipment or a mix tank. Fill the container $\frac{1}{4}$ with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure 2 more times. Then offer for recycling or reconditioning if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(For refillable containers):

Container Handling: Refillable container. Refill this container with **275 TBD** only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean the container before final disposal, empty the remaining contents into the application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Dispose of rinsate as pesticide waste. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by procedures allowed by state and local authorities.

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: **275 TBD** is not compatible with other chemicals such as acids and hydrogen peroxide.